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(71) Applicant: VIACOR, INCORPORATED [US/US]; 66 H Concord Street, Wilmington, MA 01887 (US).

(72) Inventors: LIDDICOAT, John, R.; Barberry Farm, Barberry Road, Sewickley, PA 15143 (US). LAMBRECHT, Gregory, H.; 220 Eliot Street, Natick, MA 01760 (US). DAVENPORT, Todd, F.; 48 Salem Street, Andover, MA 01801 (US). COHN, William, E.; 104 Lagrange Street, Chestnut Hill, MA 02167 (US). WOOLFSON, Steven, B.; 85 East India Road, #39G, Boston, MA 02110 (US). TAYLOR, Daniel, C.; 35 Faneuil Street, Brighton, MA 02135 (US).

(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

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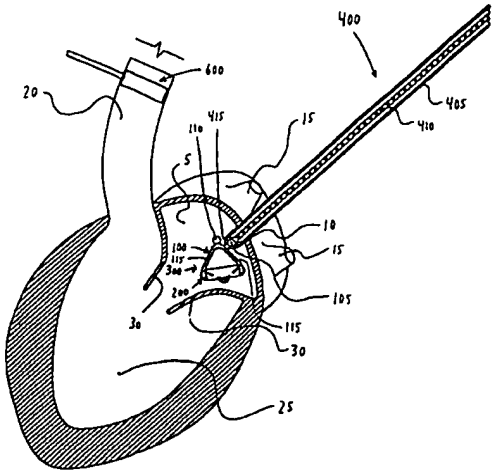

(57) Abstract: The present invention comprises a method for deploying an aortic valve prosthesis. This valve prosthesis may include any of the known aortic valves including, but not limited to, stented and unstented bioprosthetic valves, stented mechanical valves, and expandable or self-expanding valves, whether biological or artificial. The method involves the steps of: making a first opeing leading to the left atrium; passing a valve prosthesis through the opening and into a cardiac chamber of the left side of the heart using a first manipulation instrument; making a second opening in the arterial system and advancing one end of a second manipulation instrument through the arterial opening and into the aforementioned cardiac chamber; securing the second manipulation instrument to the valve prosthesis; and using the second manipulation instrument to retract at least some portion of the valve prosthesis out of the aforemetioned cardiac chamber.

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METHOD AND APPARATUS FOR PERFORMING A PROCEDURE ON A CARDIAC VALVE

Reference To Pending Prior Patent Application

This patent application claims benefit of pending prior U.S. Provisional Patent Application Serial No. 60/215,245, filed 6/30/00 for CARDIAC VALVE PROCEDURE METHODS AND DEVICES, which patent application is hereby incorporated herein by reference.

Background Of The Invention

Of all valvular heart lesions, aortic stenosis carries the worst prognosis. Within one year of diagnosis, approximately half of all patients with critical aortic stenosis have died, and by three years, this figure rises to approximately 80%. Currently, the most prominent and effective treatment for patients with aortic stenosis is aortic valve replacement via open heart surgery. Unfortunately, this procedure is a substantial and invasive undertaking for the patient.

While there have been significant advances in heart valve technology over the past 30 years, there has been little progress in the development of safer and less invasive valve delivery systems. Aortic valve replacement currently requires a sternotomy or thoracotomy, use of cardiopulmonary bypass to arrest the heart and lungs, and a large incision on the aorta. The native valve is resected through this incision and then a prosthetic valve is sutured to the inner surface of the aorta with a multitude of sutures passing only partly into the wall of the aorta. Given the current invasiveness of this procedure and the requirement to utilize cardiopulmonary bypass, aortic valve replacement surgery is associated with a high risk of morbidity and mortality. This is especially true in elderly patients, and in those patients who require concomitant coronary artery bypass grafting. Even when a good surgical result is achieved, virtually all patients require approximately 6 weeks to several months to fully recover from the procedure. In order to decrease these associated risks of aortic

valve surgery, many have pursued novel approaches and technologies.

Less invasive approaches to aortic valve surgery have generally followed two paths.

In the 1980's, there was a flurry of interest in percutaneous balloon valvotomy. In this procedure, a cardiologist introduced a catheter through the femoral artery to dilate the patient's aortic valve, thereby relieving the stenosis. Using the technology available at that time, success was limited: the valve area was increased only minimally, and nearly all patients had restenosis within one year.

More recently, surgeons have approached the aortic valve via smaller chest wall incisions. However, these approaches still require cardiopulmonary bypass and cardiac arrest, which themselves entail significant morbidity and a prolonged post-operative recovery.

The ideal minimally invasive approach to the treatment of aortic valve disease requires aortic valve replacement without cardiopulmonary bypass and

without cardiac arrest. Such an approach would greatly reduce patient morbidity and mortality and hasten recovery. Unfortunately, although there has been great progress in the treatment of coronary artery disease without cardiopulmonary bypass (e.g., angioplasty, with or without stenting, and "off-pump" coronary artery bypass grafting), similar advances have not yet been realized in heart valve surgery. With an aging population and improved access to advanced diagnostic testing, the incidence and accurate diagnosis of aortic stenosis will continue to increase. The development of a system for "off-pump" aortic valve replacement would be of significant benefit to this increasing patient population.

There are three important challenges to replacing a diseased aortic valve without cardiopulmonary bypass.

The first challenge is to remove the diseased valve without causing stroke or other ischemic events that might result from the liberation of particulate material while removing the diseased valve.

The second challenge is to prevent cardiac failure during removal of the diseased valve. In this respect it must be appreciated that the aortic valve continues to serve a critical function even when it is diseased. However, as the diseased valve is removed, it becomes acutely and severely incompetent, causing the patient to develop heart failure which results in death unless the function of the valve is taken over by another means.

The third challenge is placing a prosthetic valve into the vascular system and affixing it to the wall of the aorta. More particularly, during cardiac rhythm, the aortic and arterial pressures are substantially greater than atmospheric pressure. Therefore, any sizable incision made to the aorta in order to insert a standard valve prosthesis into the arterial system creates the potential for uncontrollable bleeding from the incision site. Furthermore, even if bleeding is successfully controlled, pressures within the aorta may result in weakening of the aorta caused by aortic wall

dissection. In addition, large incisions on the aorta also increase the potential for liberating plaque from the aortic wall that can lead to embolic complications.

For these reasons, prior art valve prostheses potentially suitable for off-pump implantation have relied upon relatively flimsy expandable structures to support and secure the valve within the aorta. More particularly, these prosthetic valves are constructed so that they can be compressed to a relatively small dimension suitable for insertion into the arterial system, advanced to the site of the aortic valve, and then expanded against the aortic wall. Unfortunately, however, none of these relatively flimsy valve prostheses have proven adequate to endure the repetitive stresses undergone by the aortic valve over the ten to twenty years typically required.

In addition to the foregoing, the precise placement of such expandable prosthetic valves in the correct sub-coronary position can be extremely challenging, particularly in view of the high

pressure, pulsatile blood flow passing through the aorta. Furthermore, expandable prosthetic valves would typically be positioned from a remote artery, which would reduce the ability to precisely control the placement and positioning of the device and therefore would increases the risk of obstructing the coronary arteries. The expandable prosthetic valves are held on the ends of elongate, flexible catheters that are threaded into the aorta, around the aortic arch and then expanded. The pulsatile flow during cardiac rhythm induces a to-and-fro motion of the valve prosthesis relative to the aorta that makes the timing of valve expansion critical for proper placement of the expandable prosthetic valve and hence the survival of the patient.

Finally, many of the challenges discussed in the foregoing section pertaining to aortic valve replacement are also relevant to other procedures in the aortic root such as aortic valve resection, aortic valve decalcification, stent grafting for aortic dissections, etc.

Summary Of The Invention

It is, therefore, one object of the present invention to enable the passage of a device from the left atrium, through the left ventricle, and into the arterial system.

Further, another object of the present invention is to enable the implantation of a device in the arterial system without cardiopulmonary bypass.

Further, another object of the present invention is to enable the implantation of a prosthetic valve in the arterial system without cardiopulmonary bypass.

Another object of the present invention is to allow the insertion of such a valve while minimizing the risks to the patient posed by large arterial incisions.

And another object of the present invention is to simplify the precise placement of such a valve.

Further, another object of the present invention is to enable the implantation of a device other than a valve, such as but not limited to a valve resection

tool, a decalcifying tool, an aortic valve repair tool, or a stented aortic graft, in the arterial system without cardiopulmonary bypass.

Another object of the present invention is to allow the insertion of a device other than a valve, such as but not limited to a valve resection tool, a decalcifying tool, an aortic valve repair tool, or a stented aortic graft, while minimizing the risks to the patient posed by large arterial incisions.

And another object of the present invention is to simplify the precise placement of a device other than a valve, such as but not limited to a valve resection tool, a decalcifying tool, an aortic valve repair tool, or a stented aortic graft.

The present invention relates to a method and apparatus for positioning a device in the arterial system. More specifically, the present invention relates to a method and apparatus for positioning an aortic valve prosthesis in the aorta or aortic outflow tract, with or without cardiopulmonary bypass.

One aspect of the present invention is a method for deploying an aortic valve prosthesis. This valve prosthesis may include any of the known aortic valves including, but not limited to, stented and unstented bioprosthetic valves, stented mechanical valves, and expandable or self-expanding valves, whether biological or artificial.

In one aspect of the invention, there is provided a method of inserting a prosthesis or device from a lower pressure region into a higher pressure region of the cardiovascular system comprising the steps of: making an opening in a wall of a lower pressure region of the cardiovascular system; advancing the prosthesis or device through the opening and into the lower pressure region; and advancing the prosthesis or device through a natural barrier between the lower pressure region and the higher pressure region.

In another aspect of the invention, there is provided a method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of: making an opening in a wall of a low

pressure region of the heart; advancing the prosthesis or device through the opening and into the low pressure region; advancing the prosthesis or device through a natural barrier between the low pressure region and the left ventricle; and advancing the prosthesis or device from the left ventricle into the arterial system and the vessel.

And in another aspect of the invention, there is provided a method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of: making an opening in a wall of the left atrium; advancing the prosthesis or device through the opening and into the left atrium; advancing the prosthesis or device through the mitral valve and into the left ventricle; and advancing the prosthesis or device from the left ventricle into the arterial system and the vessel.

And in another aspect of the present invention, there is provided a method for positioning a device in the arterial system comprising the steps of: making a first opening leading to the left atrium; passing a

valve prosthesis through the first opening and into a cardiac chamber of the left side of the heart using a first manipulation instrument; making a second opening in the arterial system and advancing one end of a second manipulation instrument through the second opening and into the aforementioned cardiac chamber; securing the second manipulation instrument to the valve prosthesis; and then using the second manipulation instrument to retract at least some portion of the valve prosthesis out of the aforementioned cardiac chamber.

An alternative method for positioning a device in the arterial system comprises the steps of: making an opening leading to the left atrium; passing a valve prosthesis through the opening and into a cardiac chamber of the left side of the heart using an articulating manipulation instrument; using the articulating manipulation instrument to guide the valve prosthesis into the arterial cardiac chamber; releasing the valve prosthesis into a desired position: and then retracting at least a portion of

the articulating manipulation instrument out of the aforementioned cardiac chamber and left atrium.

The pressure of blood flowing through the left atrium is very low, peaking at a few inches of water during the cardiac cycle. This pressure is a small fraction of that found within the arterial system and thus permits insertion of a conventional valve prosthesis through a relatively large opening formed in the wall of the left atrium without the risk of uncontrollable bleeding. In this respect it will be appreciated that various methods are known to those skilled in the art for controlling bleeding from an incision into the left atrium. The left atrium also rarely suffers from atherosclerotic plaque formation or calcification, thus minimizing the risk of embolic debris during such incision.

Another aspect of the present invention is the use of a prosthesis holding apparatus for releasably holding the valve prosthesis during manipulation to its implant site. The prosthesis holding apparatus may be secured to the prosthetic valve at any suitable

location(s) through the use of any of a variety of approaches including, but not limited to, suture loops, barbs, hooks, grasping jaws, opposing magnetic poles, friction fits and the like. The prosthesis holding apparatus is configured to provides first and second manipulation mounts for engagement by the aforementioned first and second manipulation instruments, respectively, whereby the prosthetic valve can be delivered to its implant site. This construction is highly advantageous in that it permits the valve prosthesis to be passed easily and reliably from the first manipulation instrument to the second manipulation instrument within the vascular system.

In an alternative preferred embodiment, the prosthetic holding apparatus is attached on the ventricular side of the prosthesis. The aforementioned first manipulation instrument would articulate at or near the prosthetic valve to facilitate manipulation of the prosthesis holding apparatus (and hence the prosthesis itself) through the smallest possible incision site, then through the

left atrium, the mitral valve and within the heart to align and position the prosthesis within the aortic annulus or left ventricular outflow track. In this alternative embodiment, there is no need for the aforementioned second manipulation instrument or the second manipulation mount.

In addition, if the prosthesis holding apparatus is attached on the aortic side of the prosthesis, the manipulation instrument may articulate and may be introduced into the arterial system, brought across the mitral valve into the left atrium, out the left atrium to pick up the prosthesis holding apparatus (and hence the prosthesis) and then retracted back to position the prosthesis directly into the aortic annulus without the need for another manipulation instrument.

Brief Description Of The Drawings

These and other objects and features of the present invention will be more fully disclosed or rendered obvious by the following detailed description

of the preferred embodiments of the invention, which is to be considered together with the accompanying drawings wherein like numbers refer to like elements and further wherein:

Fig. 1 is a schematic side view showing the introduction of a valve prosthesis and prosthesis holding apparatus into the left atrium of the heart, through an atriotomy, using a first manipulation instrument;

Fig. 2 is a schematic side view showing passage of the apparatus of Fig. 1 from the left atrium, through the mitral valve, and into the left ventricle;

Fig. 3 is a schematic side view showing the introduction of a second manipulation instrument into the left ventricle through an arteriotomy into the arterial system;

Fig. 4 is a schematic side view showing the second manipulation instrument being attached to the prosthesis holding apparatus while the first manipulation instrument remains secured to the prosthesis holding apparatus;

Fig. 5 is a schematic side view similar to that of Fig. 4, except showing the first manipulation instrument being removed from the surgical site while the second manipulation instrument remains secured to the prosthesis holding apparatus;

Fig. 6 is a schematic side view showing the second manipulation instrument positioning the prosthetic valve within the aorta prior to fixation;

Fig. 7 is a schematic side view showing the prosthetic valve secured to the tissues of the aorta following removal of the second manipulation instrument and prosthesis holding apparatus;

Figs. 8, 9 and 10 are enlarged schematic views showing a preferred construction for the valve holding apparatus, and for the attachment to, and detachment from, the prosthetic valve; and

Fig. 11 is a schematic view showing a guide for guiding the second manipulation instrument relative to the first manipulation instrument such that the second manipulation instrument will be aimed directly at the

second manipulation mount when the first manipulation mount is secured to the first manipulation instrument.

Detailed Description Of The Preferred Embodiments

The present invention can be used to implant a variety of prostheses into the arterial system or left side of the heart. The prosthesis used in the preferred embodiment is an aortic valve prosthesis. Alternatively, the prosthesis may comprise, but is not limited to, a cylindrical arterial stent, an arterial prosthesis or graft, a ventricular assist device, a device for the treatment of heart failure such as an intraventricular counterpulsation balloon, chordae tendinae prostheses, arterial filters suitable for acute or chronic filtration of emboli from the blood stream, arterial occlusion devices and the like.

For clarity of illustration, the present invention will hereinafter be discussed in the context of implanting an aortic valve prosthesis.

It should also be appreciated that the present invention may be practiced either "on-pump" or

"off-pump". In other words, the present invention may be performed either with or without the support of cardiopulmonary bypass. The present invention also may be performed either with or without cardiac arrest.

Looking now at Fig. 1, there is shown an exemplary embodiment of the present invention. A prothesis holding apparatus 100 is secured to a prosthetic valve 200 so as to form a temporary prosthetic assembly 300. A first manipulation instrument 400 is secured to a first manipulation mount 105 formed on prosthesis holding apparatus 100, whereby temporary prosthetic assembly 300 may be moved about by first manipulation instrument 400. Temporary prosthetic assembly 300 has been positioned in left atrium 5 by passing first manipulation instrument 400 through atriotomy 10. Alternatively, the temporary prosthetic assembly 300 could be passed into the left atrium 5, using first manipulation instrument 400, through any of the pulmonary veins 15. And in another form of the invention, temporary prosthesis assembly

300 could be passed into the left atrium by first passing the assembly into the right atrium via an atriotomy, and then into the left atrium through an incision made in the interatrial septum.

Prosthetic valve 200 is preferably a conventional mechanical aortic valve of the sort well known in the art, although other forms of valve prostheses may also be used.

In one preferred form of the invention, first manipulation instrument 400 functions by virtue of the relative motion of an outer cannula 405 relative to an inner grasper 410. More particularly, inner grasper 410 has an elastically deformable distal gripper 415 which is open when the gripper is outside of outer cannula 405. However, when deformable gripper 415 is pulled at least partially into or against outer cannula 405, gripper 415 is elastically deformed into a closed position, whereby it may grip an object, e.g., first manipulation mount 105 formed on prosthesis holding apparatus 100. First manipulation instrument 400 is shown in Fig. 1 in its closed

position, wherein deformable gripper 415 is closed about first manipulation mount 105, such that prosthesis holding apparatus 100, and hence the entire temporary prosthetic assembly 300, is held secured to the distal end of first manipulation instrument 400.

The specific embodiment of first manipulation instrument 400 shown in Fig. 1 is presented as an illustrative example only, and is not intended to limit the scope of the present invention. Many other arrangements may be used for releasably gripping first manipulation mount 105 formed on prosthesis holding apparatus 100. Furthermore, first manipulation mount 105 may itself have many potential shapes and properties to enable releasable attachment to first manipulation instrument 400. Other possible configurations for releasably securing first manipulation mount 105 to first manipulation instrument 400 include, but are not limited to, opposing magnet poles in the mount and instrument, adhesives, a press fit between mount and instrument, threaded couplings, suture loops, a balloon or

balloons expanded within a mating cavity, collapsible barbs, etc. For the purposes of the present invention, the important point is that some arrangement be provided for releasably securing the prosthesis holding apparatus (and hence the prosthetic valve) to a manipulation instrument.

Still looking now at Fig. 1, first manipulation instrument 400 is shown as having a long axis that extends outside of the heart, with first manipulation instrument 400 being straight along that axis. However, it should also be appreciated that first manipulation instrument 400 may, alternatively, be formed with a curve at one or more location along this length. Furthermore, first manipulation instrument 400 may be constructed so as to allow articulation at the distal end, the proximal end, or both, or at any point therebetween. In addition, first manipulation instrument 400 may be formed either entirely rigid or substantially flexible, along all or part of its length.

First manipulation instrument 400 is also shown as having a relatively small dimension perpendicular to its long axis. This configuration allows atriotomy 10 to be reduced in size after the passage of temporary prosthetic assembly 300 into left atrium 5. This perpendicular dimension may be constant or varied along the long axis of first manipulation instrument 400.

The specific embodiment of the prosthesis holding apparatus 100 shown in Fig. 1 is presented as an illustrative example only, and is not intended to limit the scope of the present invention. Many other arrangements may be used for releasably gripping prosthetic valve 200 and for providing first manipulation mount 105, as well as providing a second manipulation mount 110 that will be discussed below. In Fig. 1, first manipulation mount 105 and second manipulation mount 110 are shown as spherical additions to struts 115 extending away from prosthetic valve 200. These spheres are intended to fit, respectively, within the deformable gripper 415 of

first installation instrument 400 and the deformable gripper 515 of a second installation instrument 500 (discussed below). First manipulation mount 105 and/or second manipulation mount 110 could, alternatively, be indentations within a portion of male or female threaded extensions from, magnetized surfaces of, slots or holes in or through, prosthesis holding apparatus 100, etc. Furthermore, first manipulation mount 105 and/or second manipulation mount 110 could be portions of the struts 115 extending away from prosthetic valve 200, where those portions may be either reduced or enlarged in dimension relative to neighboring portions of the struts. Many other constructions may also be used to form first manipulation mount 105 and second manipulation mount 110. For the purposes of the present invention, the important point is that some arrangement be provided for releasably securing the prosthesis holding apparatus (and hence the prosthetic valve) to manipulation instruments.

Still looking now at Fig. 1, it will be appreciated that the native aortic valve has been removed. Removal of the native aortic valve is not a necessary element of the present invention, but may be incorporated into the preferred method. Removal of the native aortic valve may be accomplished either before or after passage of the temporary prosthetic assembly 300 into left atrium 5.

When the methods and devices of the present invention are employed during an off-pump valve replacement procedure, it may be beneficial to provide temporary valves and/or filters in the arterial system, downstream of the site of the native aortic valve. Thus, for example, in Fig. 2 there is shown a temporary valve 600 which may be used to support cardiac function during and following removal of the diseased cardiac valve. Temporary valve 600 is shown positioned in aorta 20. Alternatively, temporary valve 600 may be positioned in the aortic arch or the descending aorta. In addition, temporary valve 600 may incorporate a filter therein to mitigate the risks

of embolic complications. Alternatively, a separate filter may be employed within the aorta and/or the branch arteries extending therefrom.

Fig. 2 shows first manipulation instrument 400 being used to manipulate temporary prosthetic assembly 300 (and hence prosthetic valve 200) into left ventricle 25 through mitral valve 30. After temporary prosthetic assembly 300 has passed into left ventrical 25, the first manipulation instrument 400 will continue to traverse mitral valve 30; however, the reduced perpendicular cross-section of first manipulation instrument 400 will cause only minimal disruption of the function of mitral valve 30.

Fig. 3 shows the insertion of a second manipulation instrument 500 through the arterial system and into left ventricle 25. Second manipulation instrument 500 is shown being inserted through an incision 35 on aorta 20. Alternatively, second manipulation instrument 500 could be inserted into a central or peripheral artery and than advanced

into left ventricle 25. Aortic incision 35 is small relative to the atriotomy 10 formed in left atrium 5.

Bleeding through incision 35 may be readily controlled through a variety of means. These include, but are not limited to, employing a valved or un-valved arterial cannula, a purse-string suture placed around incision 35 and then pulled tight about second manipulation instrument 500, a side-arm graft sewn to aorta 20 that may be constricted about a region of second manipulation instrument 500, the use of a tight fit between a portion of second manipulation instrument 500 and aortic incision 35, etc.

Second manipulation instrument 500 is shown in Fig. 3 as being of the same form and function of first manipulation instrument 400. Again, outer cannula 505 fits around inner grasper 510, and the relative motion between grasper 510 and cannula 505 can be used to deform gripper 515 between open and closed positions. Alternatively, second manipulation instrument 500 may have any of the variety of other forms and functions

described above with respect to first manipulation instrument 400. Furthermore, second manipulation instrument 500 is preferably of a smaller dimension perpendicular to its long axis than first manipulation instrument 400 so as to reduce the risks posed by arteriotomy 35.

Fig. 4 shows second manipulation instrument 500 being secured to the second manipulation mount 110 formed on prosthesis holding apparatus 100. This is done while first manipulation instrument 400 is secured to first manipulation mount 105 formed on prosthesis holding apparatus 100, in order that temporary prosthetic assembly 300 will be under control at all times during the "hand-off" between first manipulation instrument 400 and second manipulation instrument 500.

It should be appreciated that the orientation of second manipulation mount 110 is preferably such as to enable the long axis of second manipulation instrument 500 to be substantially perpendicular to the flow area of prosthetic valve 200. This arrangement is

particularly helpful when guiding prosthetic valve 200 into its final position within aorta 20 as shown hereafter in Figs. 6 and 7.

The use of two separate manipulation instruments, and the method of passing valve prosthesis 200 from one to the other, avoids the complex manipulations of valve prosthesis 200 that would be required to position valve 200 within aorta 20 using only a single manipulation instrument introduced through the left atrium. In this respect it should be appreciated that such a "single manipulation instrument" technique has been found to be possible, however, and is best facilitated by using a manipulation instrument capable of bending or articulating at or near the site of its attachment to valve holding apparatus 100. In this respect it has been found that it can be particularly advantageous to provide a manipulation instrument capable of bending or articulating within about 4 cm or so of the point of attachment to valve holding apparatus 100. It has also been found that it can be particularly advantageous for such an articulating

instrument to be able to deflect its distal tip by an angle of between about 90 to 180 degrees from the long axis of the first manipulation instrument 400 shown in Fig. 4.

The angular offset of first manipulation mount 105 and second manipulation mount 110 is preferably set to facilitate passage of temporary prosthetic assembly 300 from left atrium 5 to aorta 20 using two substantially straight manipulation instruments, e.g., first manipulation instrument 400 and second manipulation instrument 500. This angle is preferably approximately 45 degrees. However, this angle may also be varied so as to optimize passage of different valve designs or other prostheses using curved, straight or articulating manipulation instruments from various access sites into the left atrium and arterial system. This angle may be fixed or variable on a given prosthesis holding apparatus 100.

Once second manipulation instrument 500 is safely secured to second manipulation mount 110, first

manipulation instrument 400 may be released from first manipulation mount 105 and removed from left ventricle 5, as shown in Fig. 5. Alternatively, first manipulation instrument 400 may remain secured to prosthesis holding apparatus 100 or prosthetic valve 200 by a flexible tether so as to facilitate re-attachment of first manipulation instrument 400 to valve holding apparatus 100 if necessary.

Fig. 6 shows temporary prosthesis assembly 300 being positioned by second manipulation instrument 500 at a preferred fixation site. This fixation site is preferably upstream of or proximal to the coronary arteries, although this position is not a restrictive requirement of the present invention.

Fig. 7 shows valve prosthesis 200 secured to the walls of aorta 30 and removal of second manipulation instrument 500 and prosthesis holding apparatus 100. In this respect it should be appreciated that prosthesis holding apparatus 100 is preferably wholly or partially flexible, or otherwise collapsible, so as to allow the prosthesis holding apparatus 100 to be

collapsed radially and then withdrawn through arteriotomy 35 after prosthesis holding apparatus 100 has been released from prosthetic valve 200. Alternatively, prosthesis holding apparatus 100 may be removed from the vascular system, either partially or entirely, through atriotomy 10 by first manipulation instrument 400, by a tether leading therefrom, or a separate instrument. Of course, in the situation where prosthesis holding apparatus 100 is to be removed via atriotomy 10, the prosthesis holding apparatus 100 should be appropriately mounted to prosthetic valve 200, i.e., prosthesis holding apparatus 100 should be positioned on the atriotomy side of the valve.

In Fig. 7, valve prosthesis 200 is shown secured to aorta 30 using barbs or staples 700. Barbs or staples 700 may be a component of, and/or deployed from, prosthesis holding apparatus 100, and/or valve prosthesis 200, and/or a separate fixation device. Alternatively, barbs or staples 700 may be deployed by a separate instrument inserted through the outer

surface of aorta 30, from a remote site in the arterial system, through atriotomy 10 or through some other incision into a cardiac chamber or great vessel.

Looking next at Figs. 8-10, there is shown one preferred configuration for prosthesis holding apparatus 100. More particularly, prosthesis holding apparatus 100 comprises a base 120 having a longitudinal opening 123 (Fig. 9) therein for slidably receiving a rod 125 therethrough. Base 120 also comprises a plurality of side slots 130. Each side slot 130 has a strut 115 pivotally connected thereto. Slots 130 are constructed so that each strut 115 can pivot freely between (i) the position shown in Figs. 8 and 9, and (ii) the position shown in Fig. 10. A body 135 is mounted on rod 125. A plurality of wire fingers 140 are secured to body 135. Wire fingers 140 extend through holes 145 formed in base 120 and extend around the cuff 205 of prosthetic valve 200. Second manipulation mount 110 is secured to the proximal end of rod 125. First manipulation mount 105 is secured to one of the struts 115. Alternatively, as noted

above, first manipulation mount 105 may be formed by a strut 115 itself, provided that first manipulation instrument 400 is appropriately adapted to engage the strut 15 directly.

In use, prosthesis holding apparatus 100 is fit about valve prosthesis 200 so that wire fingers 140 hold valve cuff 205 to struts 115. Prosthesis holding apparatus 100 is then engaged by first manipulation instrument 400, using first manipulation mount 105, and moved into and through right atrium 5, through mitral valve 30 and into left ventricle 25. Then second manipulation tool 500, comprising outer cannula 505 and inner grasper 510 having the deformable gripper 515, engages second manipulation mount 110. The distal tip 520 of outer cannula 505 is placed against edge 150 of base 120 and gripper 515 is drawn proximally within outer cannula 505 until deformable gripper 515 engages shoulder 525, whereupon prosthesis holding apparatus 100 (and hence prosthetic valve 200) will be mounted to second manipulation tool 500. Second manipulation tool 500 is then used to maneuver

temporary prosthetic assembly 300 into position, whereupon the valve's cuff 205 is secured to the side wall of the aorta, e.g., with barbs, staples, suture, etc. Then prosthesis holding apparatus 100 is detached from prosthetic valve 200 by pulling inner grasper 510 proximally relative to outer cannula 505 so that wire fingers 140 are pulled past valve cuff 205 (Fig. 9), whereby to free prosthesis holding apparatus 100 from the prosthetic valve 200. Then second manipulation instrument 500 is withdrawn out aorta 20 and arteriotomy 35, with struts 115 folding inwardly (Fig, 10) so as to pass through the arteriotomy. Struts 115 can be adapted to fold inwardly through engagement with the walls of the arteriotomy 35 or, alternatively, additional means (such as springs, cams, etc.) can be provided to fold struts 115 inwardly.

In practice, it has been found that it can sometimes be difficult to locate second manipulation mount 110 with second manipulation instrument 500 so as to "hand off" temporary prosthesis assembly 300

from first manipulation instrument 400 to second manipulation instrument 500. This can be particularly true where the procedure is to be conducted "off-pump", i.e., without stopping the heart. To this end, and looking now at Fig. 11, there is shown a guide 800 for guiding second manipulation instrument 500 relative to first manipulation instrument 400 such that second manipulation instrument 500 will be aimed directly at second manipulation mount 110 when first manipulation mount 105 is secured to first manipulation instrument 400. More particularly, guide 800 comprises a first passageway 805 for slidably receiving first manipulation instrument 400, and a second passageway 810 for slidably receiving second manipulation instrument 500. Passageways 805 and 810 are oriented so that second manipulation instrument 500 will be aimed directly at second manipulation mount 110 when temporary prosthesis assembly 300 is held by first manipulation instrument 400 engaging first manipulation mount 105.

In accordance with the present invention, it is also possible to enter the left atrium other than through an exterior wall of the left atrium. Thus, for example, it is possible to introduce the prosthetic valve through an opening in an exterior wall of the right atrium, pass the prosthetic valve through an incision in the interatrial septum and across to the left atrium, and then advance the prosthetic valve to its implantation site via the mitral valve and the left ventricle.

As noted above, the manipulation instrument(s) do not need to take the form of the installation instrument 400 or 500. It is also possible to deliver the prosthetic valve to its implant site using a guidewire and a pusher tool riding on the guidewire.

Thus, for example, in an alternative preferred embodiment, a wire, a catheter, a tube or any other filament can be placed from the left atrium, through the ventricle and into the arterial system, over (or through) which a prosthesis or device can be advanced (pushed or pulled). As an example, a catheter with a

balloon can be placed through an incision in the left atrial wall. The balloon can be inflated and this catheter can then be "floated" along the flow of blood across the mitral valve, into the left ventricle, and out into the arterial system. At that point the catheter can be grasped by an instrument placed through a small incision in the aorta or passed into the aorta by means of a remote vessel such as the femoral artery. At this point, the prosthesis or device can be mounted onto the catheter and either be pushed (or pulled) over the catheter into position. This procedure can be similarly performed by the use of a wire or other filament structure. Also, a tube could be employed, with the prosthesis or device being advanced within the tube.

What Is Claimed Is:

1. A method of inserting a prosthesis or device from a lower pressure region into a higher pressure region of the cardiovascular system comprising the steps of:

making an opening in a wall of a lower pressure region of the cardiovascular system;

advancing the prosthesis or device through the opening and into the lower pressure region; and

advancing the prosthesis or device through a natural barrier between the lower pressure region and the higher pressure region.

2. The method of claim 1 wherein the lower pressure region comprises at least one from the group consisting of the left atrium, the right atrium, a pulmonary vein, the pulmonary artery, and the venous system.

3. The method of claim 1 wherein the higher pressure region comprises at least one from the group consisting of the left ventricle, the right ventricle and the arterial system.

4. The method of claim 1 wherein the natural barrier comprises at least one of the group consisting of a valve, a wall between chambers of the heart, and the venous system.

5. The method of claim 4 wherein the valve is a cardiac valve.

6. The method of claim 5 wherein the cardiac valve is an atrioventricular valve.

7. The method of claim 6 wherein the cardiac valve is the mitral valve.

8. The method of claim 6 wherein the cardiac valve is the tricuspid valve.

9. The method of claim 5 wherein the cardiac valve is the aortic valve.

10. The method of claim 5 wherein the cardiac valve is the pulmonic valve.

11. The method of claim 4 wherein the wall between chambers of the heart comprises at least one from the group consisting of the interatrial septum and the interventricular septum.

12. A method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of:

making an opening in a wall of a low pressure region of the heart;

advancing the prosthesis or device through the opening and into the low pressure region;

advancing the prosthesis or device through a natural barrier between the low pressure region and the left ventricle; and

advancing the prosthesis or device from the left ventricle into the arterial system and the vessel.

13. The method of claim 12 wherein the natural barrier comprises at least one from the group consisting of the mitral valve and the interatrial septum.

14. The method of claim 12 wherein the wall is the external wall of the left atrium, and the natural barrier is the mitral valve.

15. The method of claim 12 wherein the wall is the wall of the right atrium, and the natural barrier is the interatrial septum and the mitral valve.

16. A method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of:

making an opening in a wall of the left atrium;

advancing the prosthesis or device through the opening and into the left atrium;

advancing the prosthesis or device through the mitral valve and into the left ventricle; and

advancing the prosthesis or device from the left ventricle into the arterial system and the vessel.

17. The method of claim 16 further comprising the use of first and second manipulation instruments for advancing the prosthesis or device, wherein:

the first manipulation instrument is used to advance the prosthesis or device through the opening, into the left atrium, through the mitral valve and into the left ventricle; and

the second manipulation instrument, passing through a second incision into the arterial system and advanced into the left ventricle, is used to advance

the prosthesis or device from the left ventricle into the arterial system and the vessel.

18. The method of claim 16 wherein the prosthesis or device is an aortic valve prosthesis.

19. The method of claim 16 wherein the vessel is the aorta.

20. The method of claim 16 further comprising the use of a manipulation instrument capable of advancing the prosthesis or device and articulating in a region near the attachment site of the manipulation instrument to the prosthesis or device, wherein the manipulation instrument is used to advance the prosthesis or device into the left ventricle and is then articulated at said region in order to allow advancement of the prosthesis or device into the arterial system.

21. A method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of:

making an opening in a pulmonary vein;

advancing the prosthesis or device through the opening into the left atrium;

advancing the prosthesis or device through the mitral valve and into the left ventricle; and

advancing the prosthesis or device from the left ventricle into the arterial system and to the vessel.

22. A method of inserting a prosthesis or device into a vessel within the arterial system comprising the steps of:

making an opening into the right atrium;

advancing the prosthesis through this incision;

making an opening in the interatrial septum;

advancing the prosthesis through this opening in the interatrial septum;

advancing the prosthesis or device through the opening into the left atrium;

advancing the prosthesis or device through the mitral valve and into the left ventricle; and

advancing the prosthesis or device from the left ventricle into the arterial system and to the vessel.

23. A method for inserting a prosthesis or device into a vessel within the arterial system comprising the steps of:

inserting a manipulation instrument into the left ventricle;

advancing the manipulation instrument through the mitral valve and into the left atrium;

attaching the prosthesis or device onto the manipulation instrument; and

withdrawing the manipulation instrument out of the left atrium, across the mitral valve and into the left ventricle.

24. The method of claim 16 wherein the prosthesis or device is releasably attached to a prosthesis holding apparatus as the prosthesis or

device is advanced through the left atrium and the left ventricle to the vessel.

25. The method of claim 16 wherein the prosthesis holding apparatus and the attached prosthesis are advanced by means of a manipulation instrument to which the prosthesis holding apparatus is releasably attached.

26. An apparatus for deploying an arterial prosthesis comprising:

a flexible holder having means for engaging and supporting an arterial prosthesis; and

at least one mount projecting from said holder in position to be releasably engaged by a manipulation instrument.

27. An apparatus according to claim 26 wherein said holder has two mounts projecting therefrom at different angles relative to said prosthesis.

28. An apparatus according to claim 26 wherein said holder has a substantially conical shape.

29. An arterial prosthesis assembly for deploying an arterial prosthesis for implantation in an arterial vessel, said assembly comprising:

an arterial prosthesis adapted for implantation in a vessel within an arterial system; and

a holder having means for releasably engaging and supporting said arterial prosthesis, and at least one mount for attachment to a manipulation instrument, said mount projecting outwardly from said holder.

30. An arterial prosthesis assembly according to claim 29 wherein said holder has two mounts for attachment to a manipulation instrument, said mounts projecting outwardly from said holder at different angles relative to said prosthesis.

31. An arterial prosthesis assembly according to claim 30 wherein said prosthesis is an arterial valve prosthesis.

32. An arterial prosthesis assembly according to claim 31 wherein said prosthesis is an aortic valve prosthesis.

33. An arterial prosthesis assembly to claim 29 wherein said prosthesis has a flow orifice, and said mount is aligned with said orifice.

34. An arterial prosthesis assembly according to claim 29 wherein said mount comprises a spherical termination.

35. An arterial prosthesis assembly according to claim 34 wherein said holder comprises a hollow conically-shaped body with an open end, and said prosthesis is attached to said holder at said open end.

36. An arterial prosthesis assembly for deploying an arterial prosthesis for implantation in an arterial vessel, said assembly comprising:

an arterial prosthesis adapted for implantation in a vessel within an arterial system, said prosthesis comprising an annular portion defining an orifice; and

a holder having first and second means for releasably supporting said arterial prosthesis, said first means releasably engaging said annular portion on a first side of said orifice and said second means extending through said orifice and releasably engaging said annular portion on a second side of said orifice, whereby said first and second means exert opposing forces on said annular portion to prevent movement of said prosthesis relative to said holder.

37. An assembly according to claim 36 wherein each of said first and second means engage said annular portion at a plurality of circumferentially spaced points.

38. An assembly according to claim 36 wherein said holder comprises a central portion and said first means comprises a plurality of arms pivotally attached to said central portion.

39. An assembly according to claim 38 wherein said arms are pivotable between a first retracted position in which they extend substantially parallel to the center axis of said central portion and a second expanded position in which they extend at an acute angle to said central portion.

40. An assembly according to claim 39 wherein said arms have first ends pivotally connected to said central portion and second ends that are adapted to engage said annular portion of said prosthesis.

41. An assembly according to claim 40 wherein said second means comprises a plurality of spring

fingers having curved outer ends that engage said annular portion of said prosthesis.

42. A holder for an arterial prosthesis comprising:

a hollow center member having first and second opposite ends;

a plurality of supporting arms mutually spaced about the center axis of said center member, said arms having inner and outer ends and being pivotally attached to said center member adjacent said first end of said center member so that said arms can pivot between a first retracted position in which said outer ends lie close to said center member and a second extended position in which said outer ends are spaced from said center member;

an actuating shaft having first and second opposite ends, said actuating shaft being slidably disposed within said center member and movable between first and second limit positions relative to said center member;

means acting between said actuating shaft and said inner ends of said arms for causing said arms to pivot to said first retracted position from said second extended position when said actuating shaft is moved from its second limit position to its first limit position and for causing said arms to pivot to said second extended position from said first retracted position when said actuating shaft is moved from its said first limit position to its said second limit position; and

a plurality of spring fingers mutually spaced about the center axis of said center member, said fingers each having first and second ends, with said first ends attached to said actuating shaft and said second ends projecting beyond the said first end of said center member, said second ends of said spring fingers being curved outwardly from said center axis of said center member, whereby said outer ends of said arms and said second ends of said spring fingers can coact to grip a prosthesis.

43. A holder according to claim 42 further including means for biasing said spring fingers so as to move said second ends of said spring fingers inwardly toward said center axis of said center member when said actuating shaft is moved to its first limit position.

44. The method of claim 1 wherein a filament is positioned in the left atrium, advanced across the mitral valve, and advanced across the left ventricle and into the arterial system and the vessel, and further wherein the prosthesis or device is advanced along the filament from the left atrium to the vessel.

45. The method of claim 1 wherein a tube is positioned in the left atrium, advanced across the mitral valve, and advanced across the left ventricle and into the arterial system and the vessel, and further wherein the prosthesis or device is advanced within the tube from the left atrium to the vessel.

46. A system for deploying an arterial prosthesis comprising:

a first manipulation instrument for attachment to the arterial prosthesis;

a second manipulation instrument for attachment to the arterial prosthesis; and

a guide for directing the second manipulation instrument to the arterial prosthesis when the arterial prosthesis is attached to the first manipulation instrument, said guide comprising a first mount for mounting said first manipulation instrument to said guide, and a second mount for mounting said second manipulation instrument to said guide, said second mount being configured relative to said first mount so as to direct said second manipulation instrument at the arterial prosthesis when the arterial prosthesis is held by said first manipulation instrument and said first manipulation instrument is mounted to said first mount.

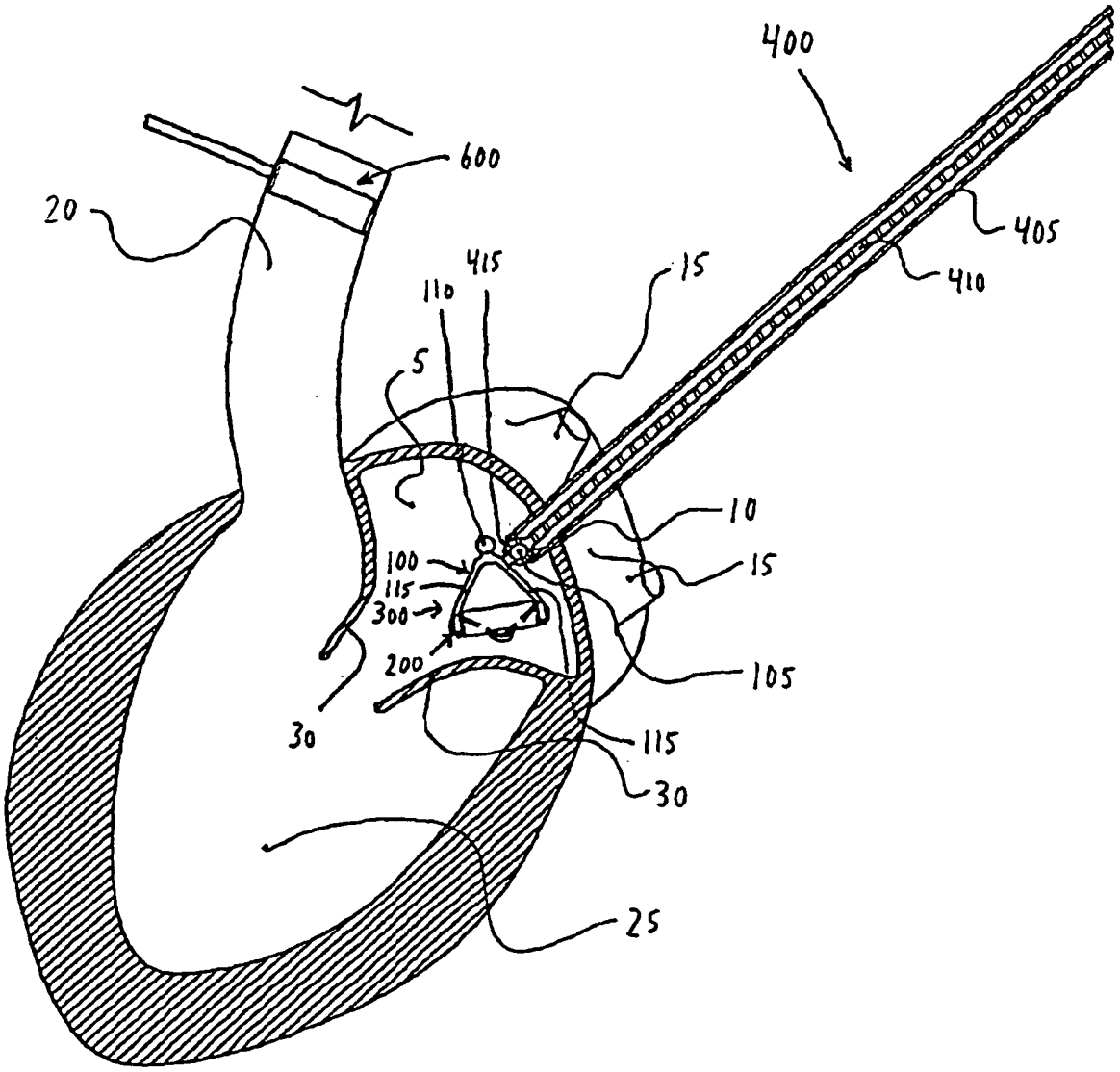
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FIG. 1

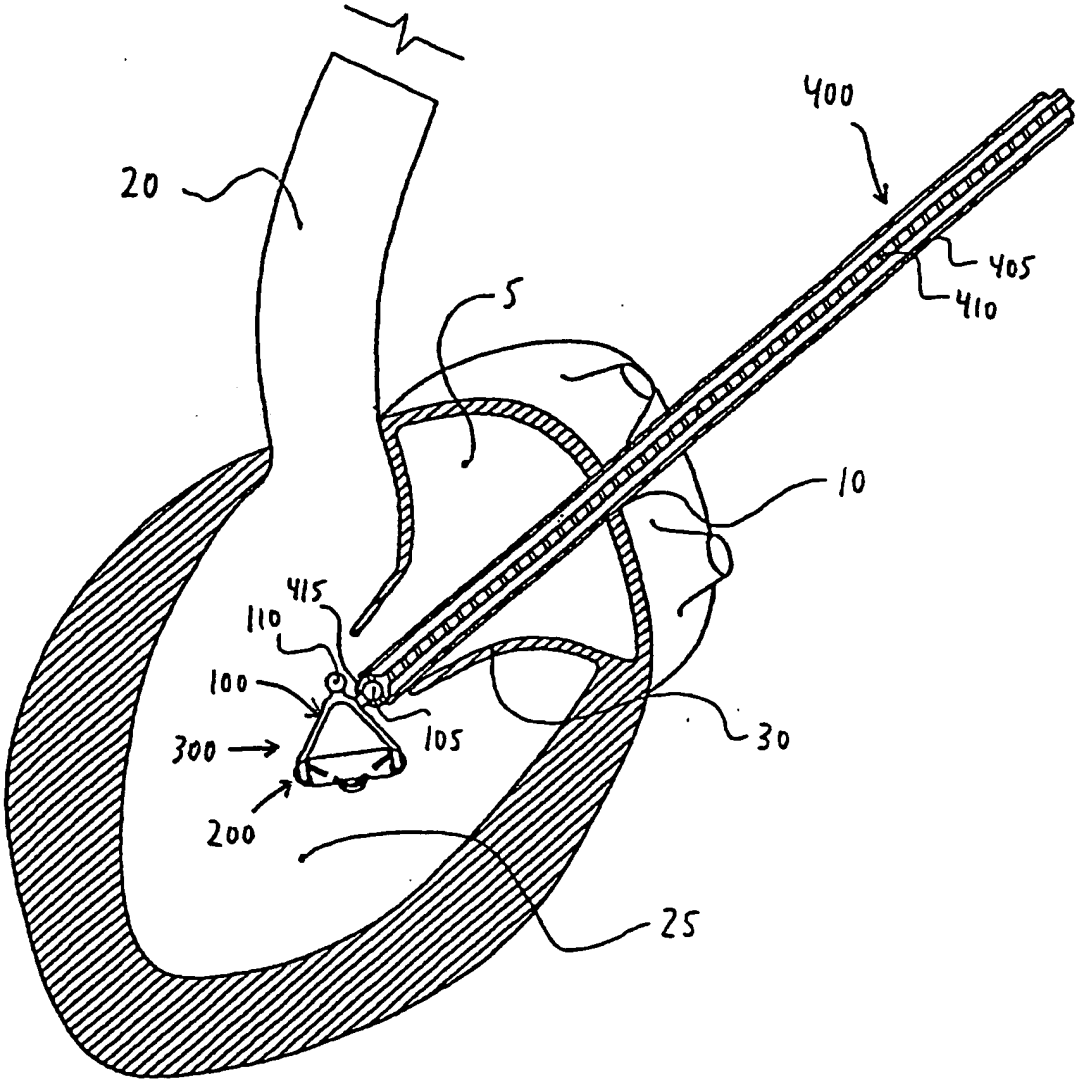

FIG. 2

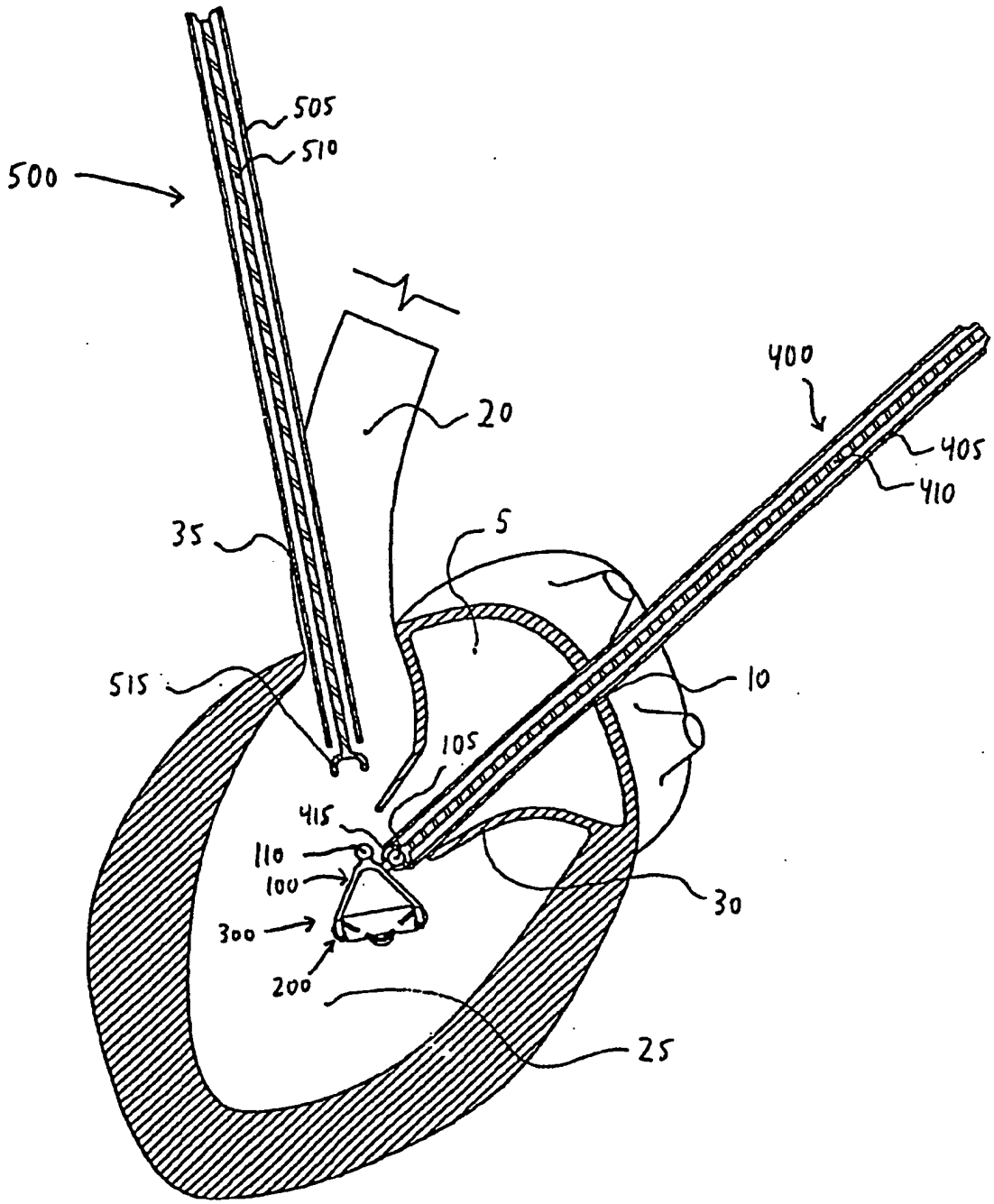
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FIG. 3

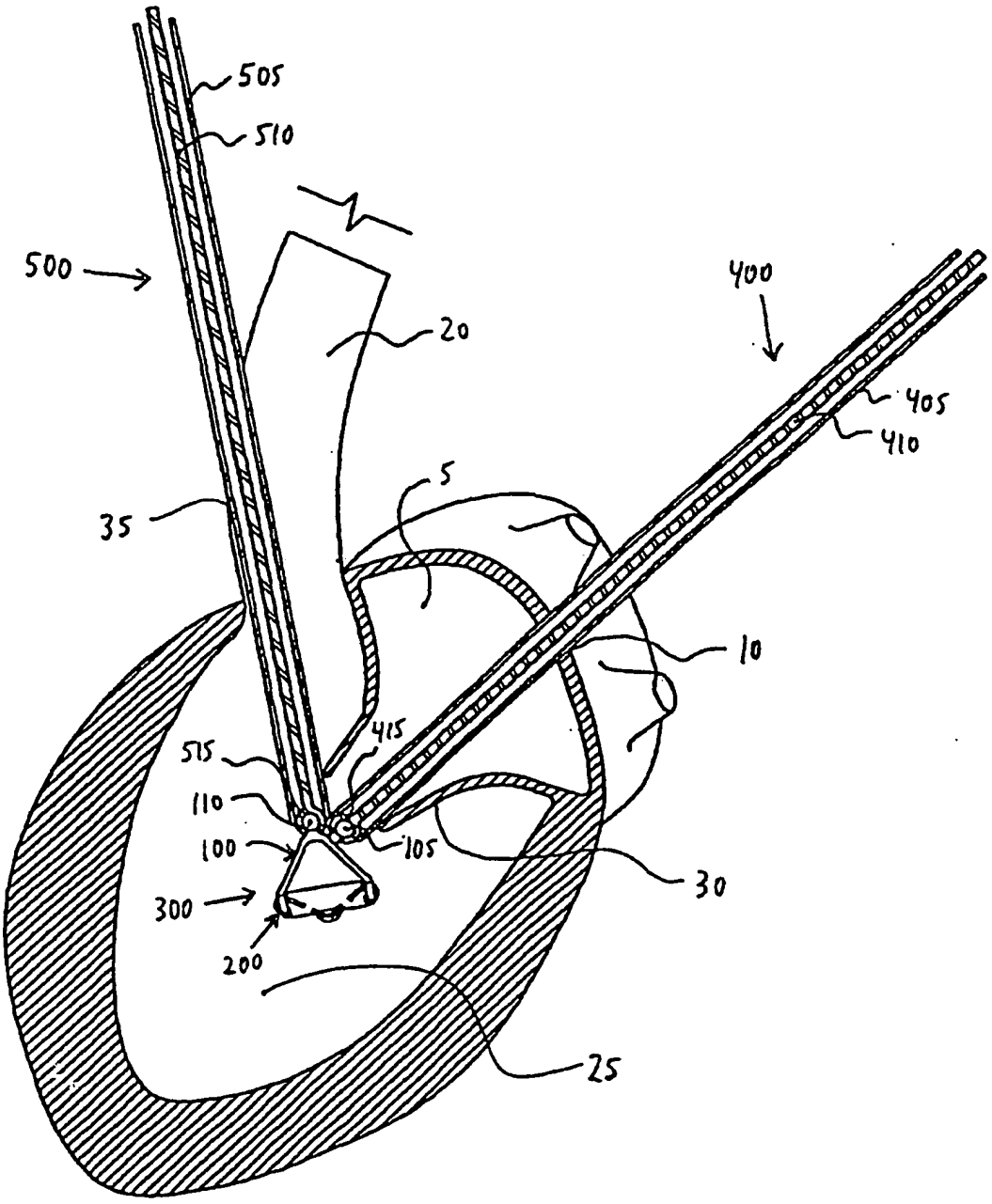
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FIG. 4

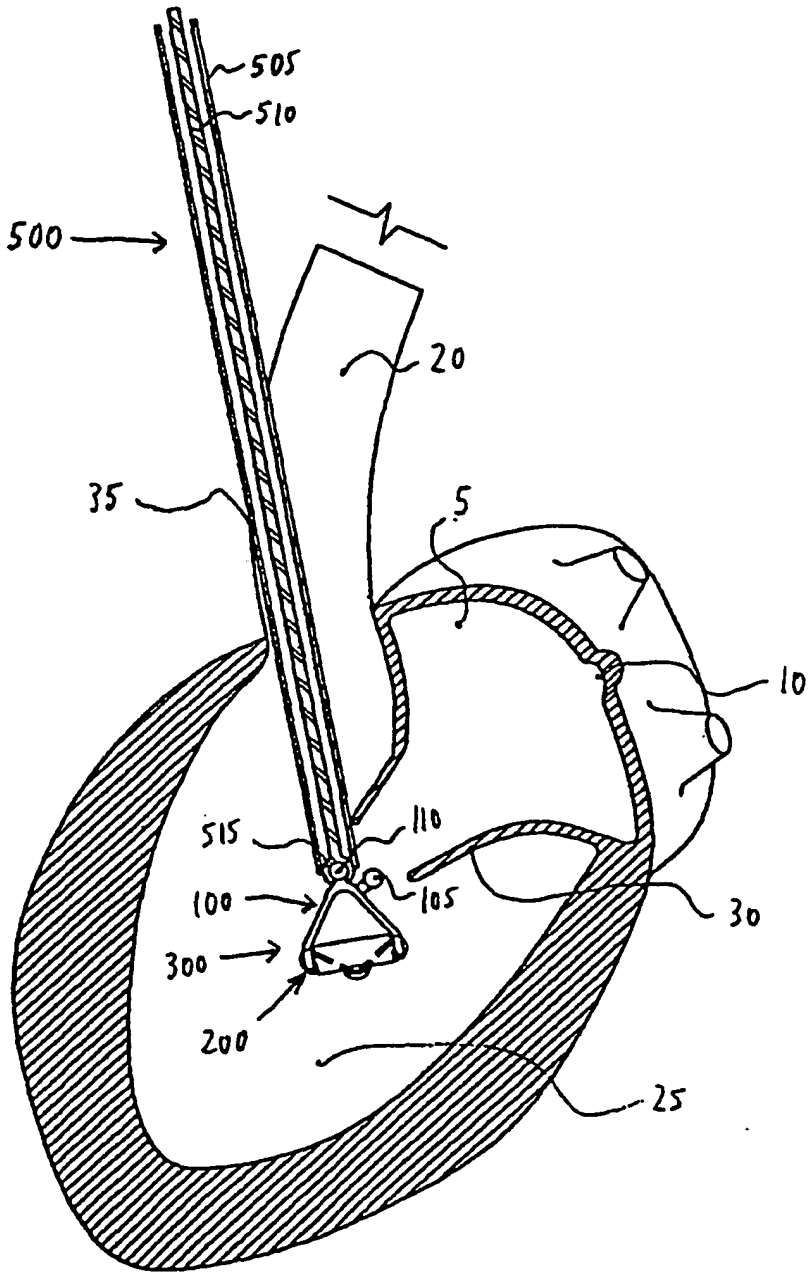


FIG. 5

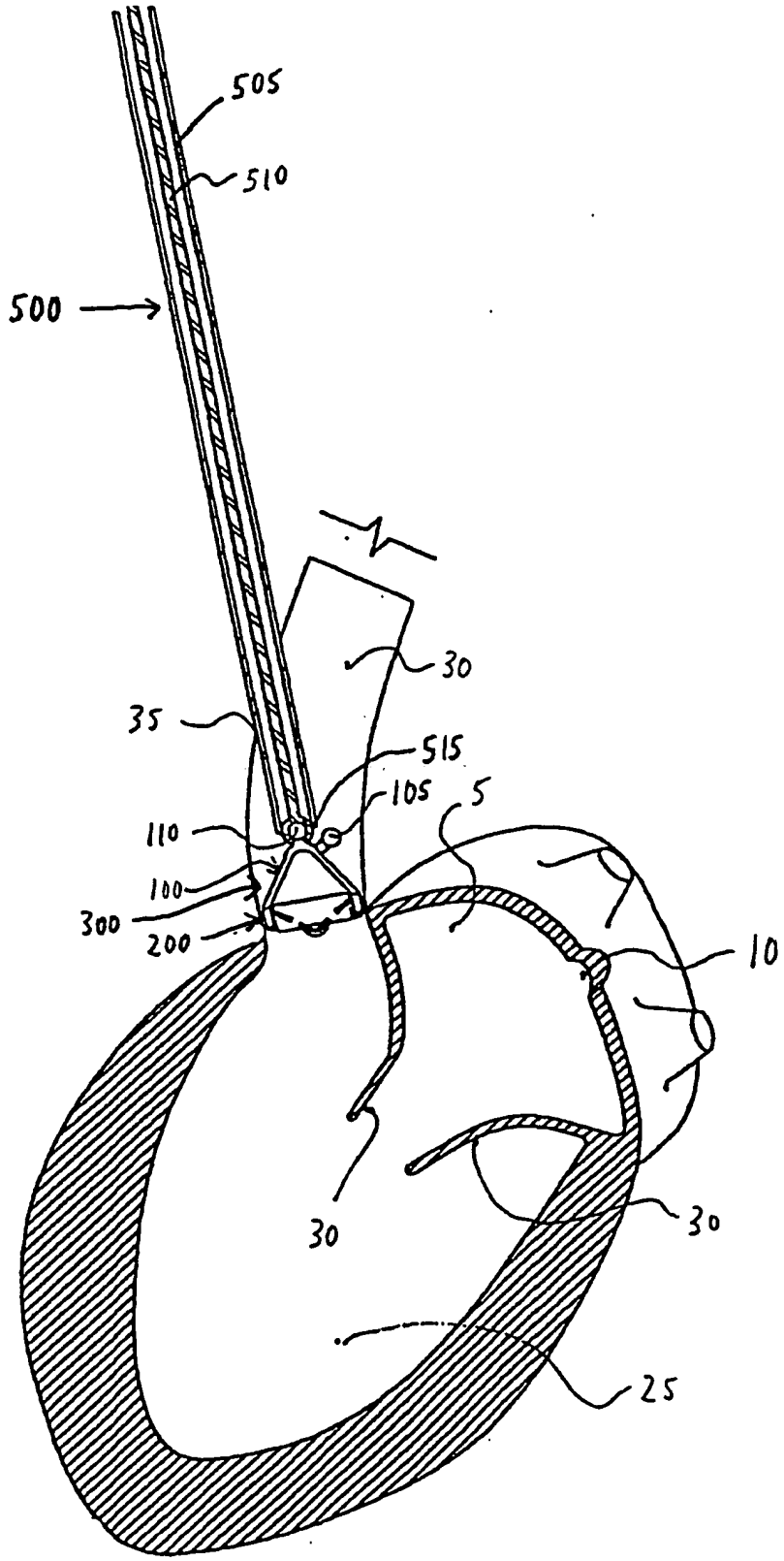


FIG. 6

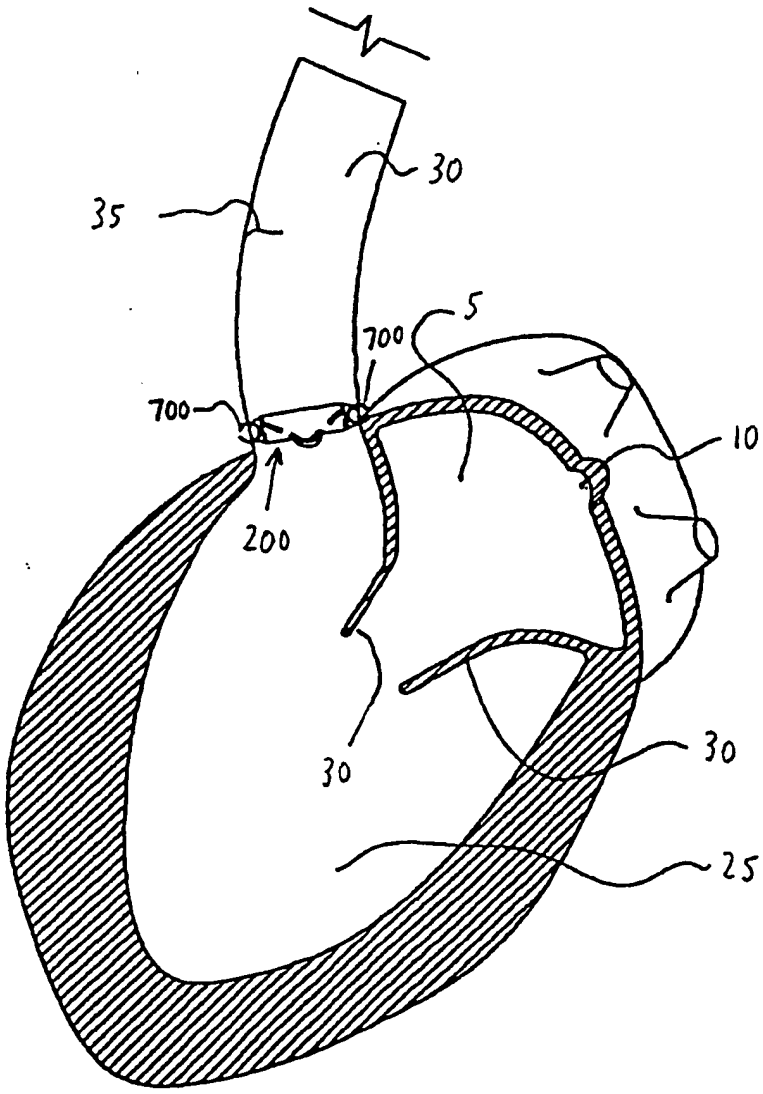
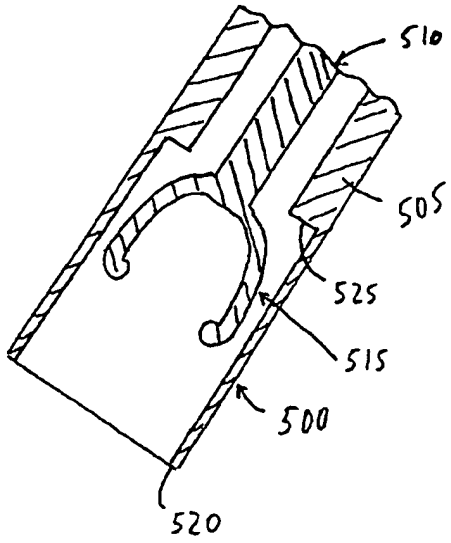


FIG. 7



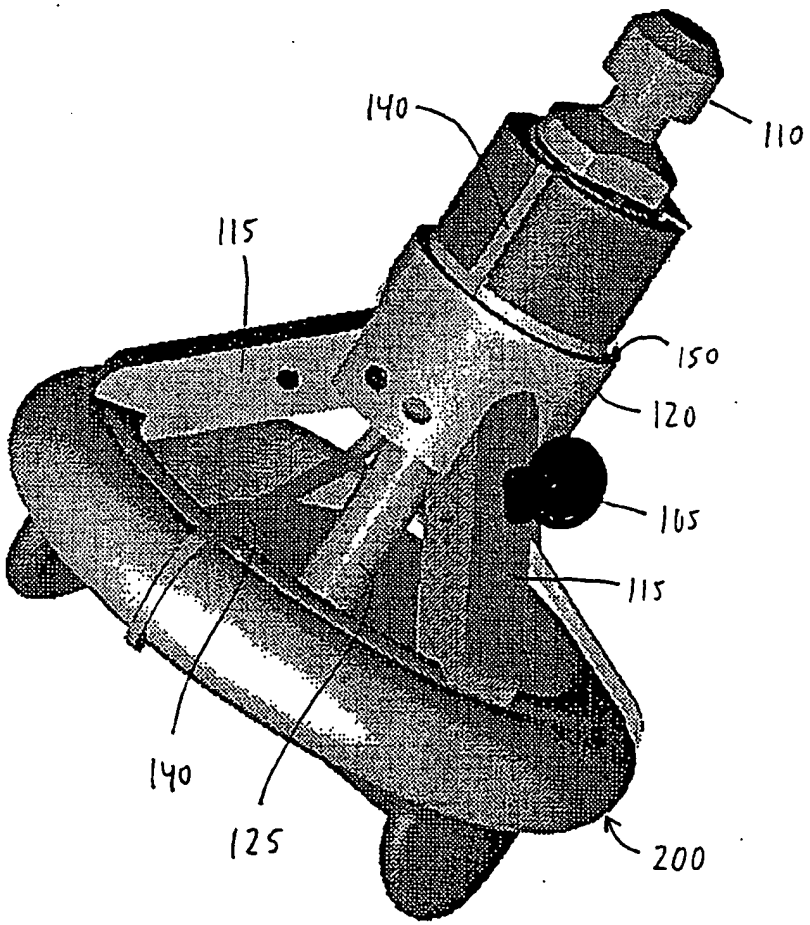


FIG. 8

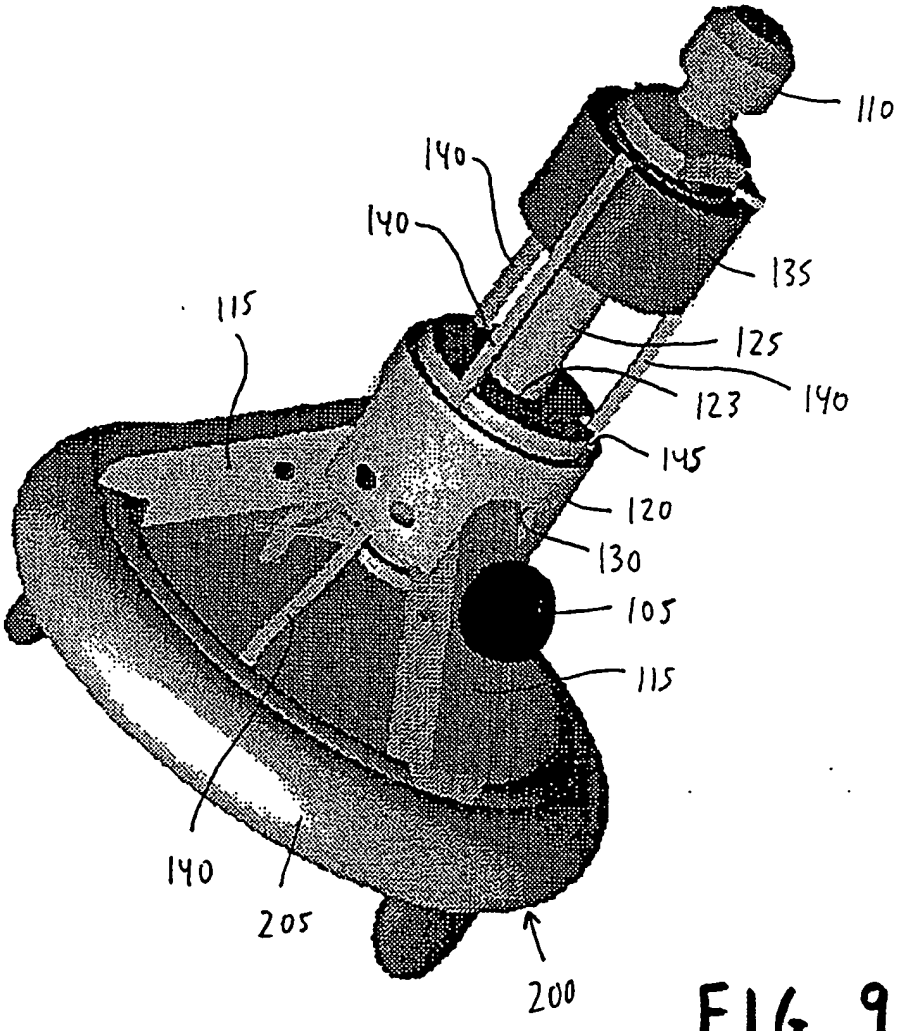


FIG. 9

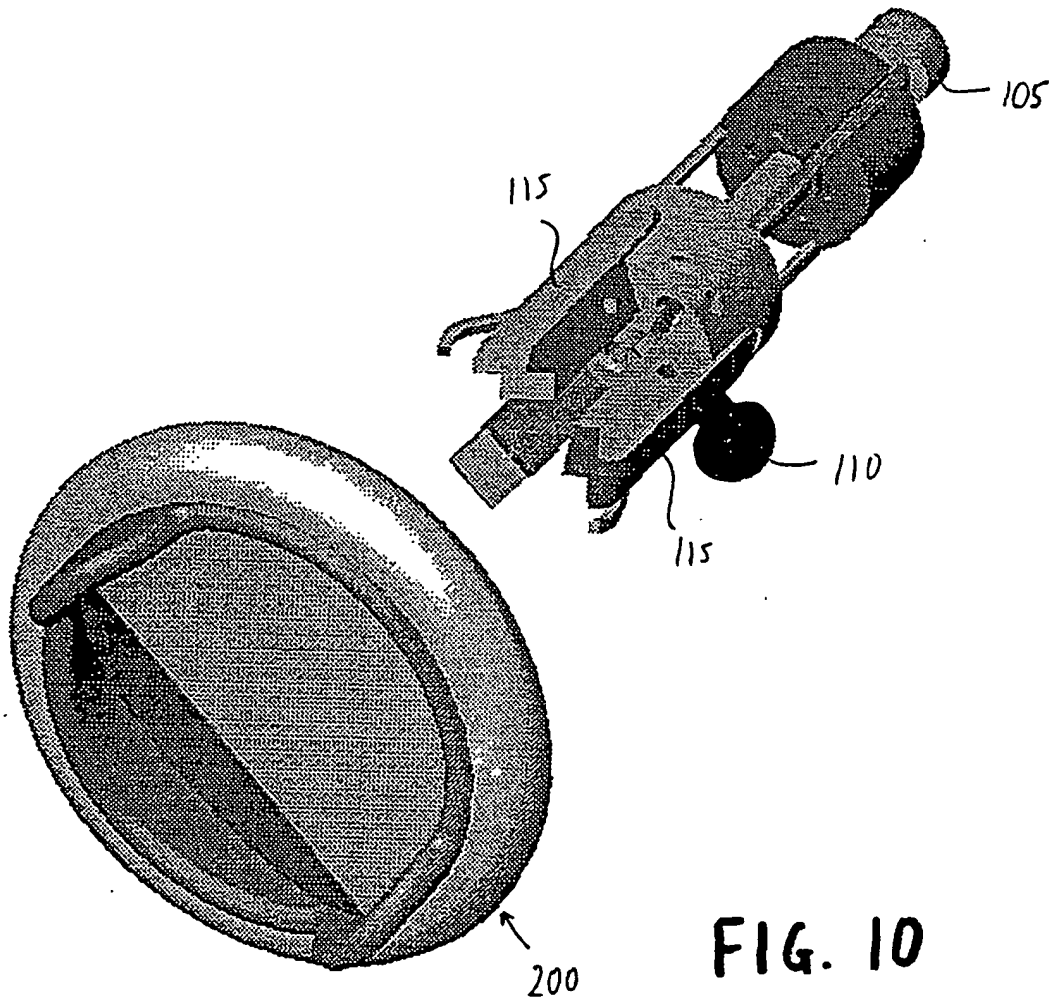


FIG. 10

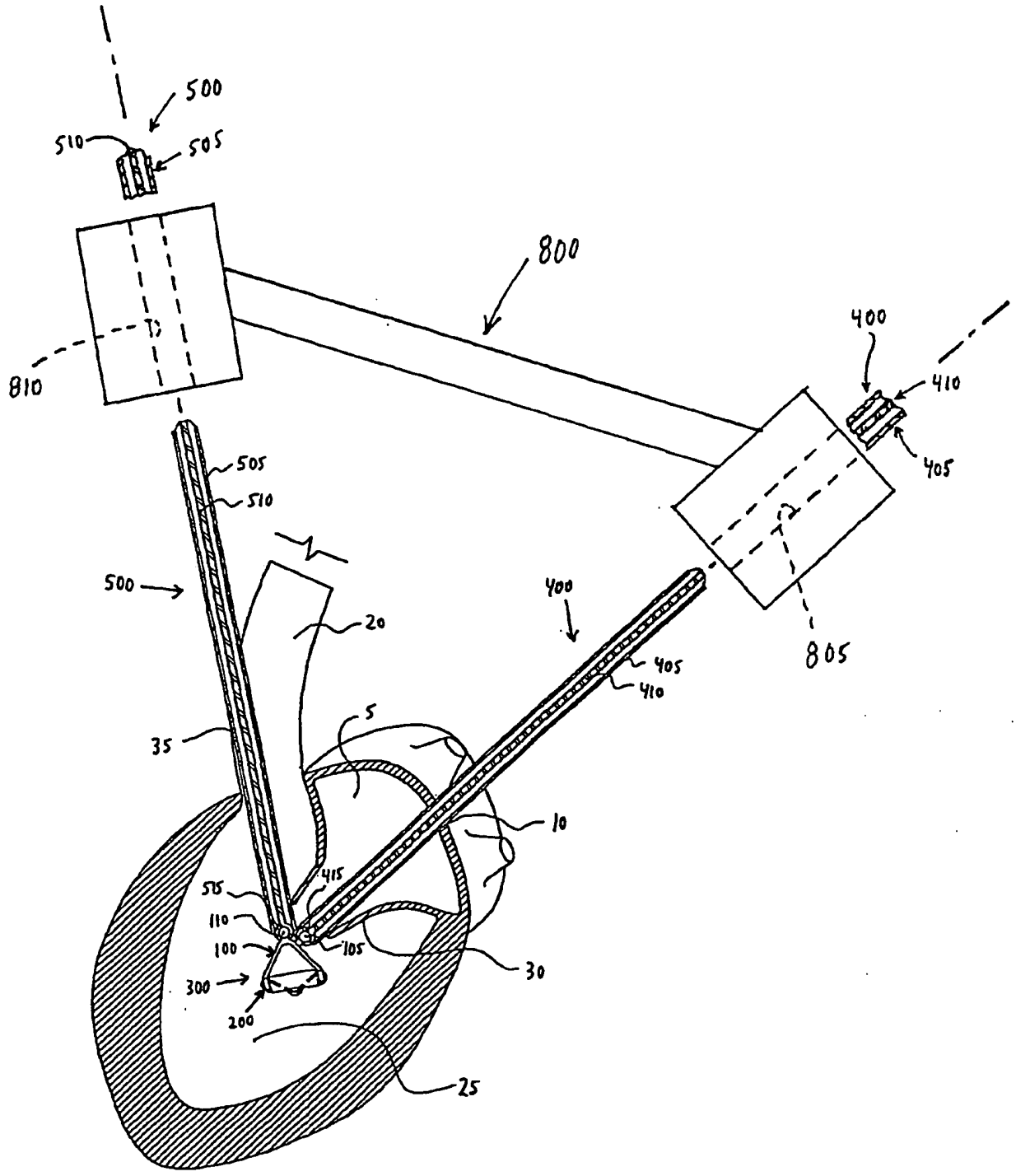

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FIG. 11

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(71) Applicant: VIACOR, INCORPORATED [US/US]; 66 H Concord Street, Wilmington, MA 01887 (US).

(72) Inventors: LIDDICOAT, John, R.; Barberry Farm, Barberry Road, Sewickley, PA 15143 (US). LAMBRECHT, Gregory, H.; 220 Eliot Street, Natick, MA 01760 (US). DAVENPORT, Todd, F.; 48 Salem Street, Andover, MA 01801 (US). COHN, William, E.; 104 Lagrange Street, Chestnut Hill, MA 02167 (US). WOOLFSON, Steven, B.; 85 East India Road, #39G, Boston, MA 02110 (US). TAYLOR, Daniel, C.; 35 Faneuil Street, Brighton, MA 02135 (US).

(74) Agent: PANDISCIO, Mark, J.; Pandiscio & Pandiscio, 470 Totten Pond Road, Waltham, MA 02451-1914 (US).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU, ZA, ZW.

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Published:
— *with international search report*
— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) Date of publication of the international search report:
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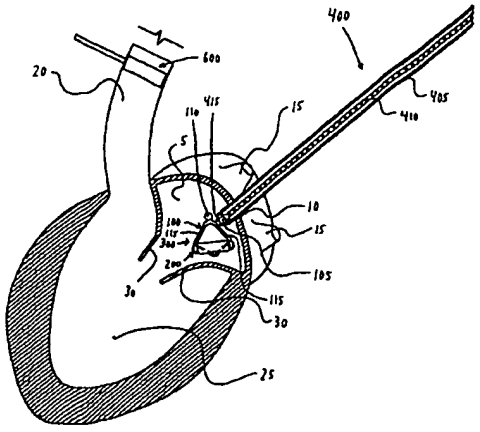
For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: METHOD AND APPARATUS FOR PERFORMING A PROCEDURE ON A CARDIAC VALVE



(57) Abstract: The present invention comprises a method for deploying an aortic valve prosthesis (200). This valve prosthesis (200) may include any of the known aortic valves including, but not limited to, stented and unstented bioprosthetic valves, stented mechanical valves, and expandable or self-expanding valves, whether biological or artificial. The method involves the steps of: making a first opeing leading to the left atrium (5); passing a valve prosthesis (200) through the opening and into a cardiac chamber of the left side of the heart using a first manipulation instrument (400); making a second opening in the arterial system and advancing one end of a second manipulation instrument (500) through the arterial opening and into the aforementioned cardiac chamber; securing the second manipulation instrument (500) to the valve prosthesis (200); and using the second manipulation instrument (500) to retract at least some portion of the valve prosthesis (200) out of the aforemetioned cardiac chamber.

WO 2002/001999 A3

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/20809

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 19/00; A61F 2/06
US CL : 623/1.11, 2.11, 902; 128/898

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.11, 1.23, 1.24, 2.11, 902; 128/898; 606/108; 600/16, 37

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,716,370 A (WILLIAMSON, IV et al) 10 February 1998 (10.02.1998), column 7, lines 13-15; column 11, lines 44-58; columns 15-16, lines 58-38; columns 16-17, lines 55-8; column 16, lines 43-45; column 17, lines 1-2; Figures 19A-19B.	1-8,11-14,16,18,19,24,25 --- 9,10,15,44
Y --- A	US 6,010,531 A (DONLON et al) 04 January 2000 (04.01.2000), columns 28-29, lines 59-8; Figure 32.	20 --- 21,22
X --- Y	US 5,041,130 A (COSGROVE et al) 20 August 1991 (20.08.1991), Figures 3, 5, 6; column 6, lines 47-61.	26-33,36,37 --- 34,35
X	US 5,972,030 A (GARRISON et al) 26 October 1999 (26.10.1999), see entire document, especially Figure 16.	26,29,36,37

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search
23 October 2003 (23.10.2003)

Date of mailing of the international search report
20 NOV 2003

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Facsimile No. (703)305-3230

Authorized officer
Urmi Chattopadhyay

Telephone No. (703) 308-8510

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/20809

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☒ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I, claim(s) 1-25, 44, 45, drawn to a method for inserting a prosthesis.

Group II, claim(s) 26-43, drawn to an apparatus for deploying an arterial prosthesis.

Group III, claim(s) 46, drawn to a system for deploying an arterial prosthesis.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: all of the groupings are directed to a method, apparatus, or system for inserting or deploying an arterial prosthesis, but each group has a different special technical feature not shared by the remaining groups. Group I is directed to a method which has the special technical feature of making an opening in a wall of a low pressure region of the cardiovascular system not shared by any of the remaining groups. Group II is directed to an apparatus which has the special technical feature of a holder not shared by any of the remaining groups. Group III is directed to a system which has the special technical feature of a guide not shared by any remaining groups.